REMARKS

In the Office Action mailed from the United States Patent and Trademark Office February 28, 2007, the Examiner rejected claims 1, 6 and 15 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,391,005 to Lum et al. (hereinafter "Lum") in view of U.S. Patent Application Publication No. 2003/0055357 to Rentea (hereinafter "Rentea"), rejected claim 2 under 35 U.S.C. § 103(a) as being unpatentable over Lum and Rentea in view of U.S. Patent No. 3,784,908 to Anderson (hereinafter "Anderson"), rejected claims 3-4, 7 and 11 under 35 U.S.C. § 103(a) as being unpatentable over Lum and Rentea in view of Lum, rejected claim 5 under 35 U.S.C. § 103(a) as being unpatentable over Lum and Rentea in view of U.S. Patent Application Publication No. 2004/0133081 to Teller et al. (hereinafter "Teller"), rejected claims 8, 10 and 12 under 35 U.S.C. § 103(a) as being unpatentable over Lum, Rentea, and Lum in view of Anderson, and rejected claims 9 and 13-14 under 35 U.S.C. § 103(a) as being unpatentable over Lum, Rentea, and Lum in view of Anderson and Teller. Applicants respectfully provide the following:

Applicants respectfully submit that the claim set as provided herein is not made obvious by the cited references. The standard for a Section 103 rejection is set forth in M.P.E.P 706.02(j), which provides:

> To establish a *prima facie* case of obviousness, three basic criteria must be met. First there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Applicants respectfully submit that there is no suggestion or motivation to combine the references in the manner suggested by the Examiner, and that one of skill in the art would not reasonably expect success in combining the references in the manner provided.

All rejections made by the Examiner rely on a combination of at least Lum and Rentea. Applicants respectfully submit that there is no motivation to combine the references contained in the references themselves, and that one of skill in the art would never think to make a combination of Lum and Rentea as they are directed to completely different purposes that are incompatible with each other. Indeed, an attempted combination of Lum and Rentea would destroy the function of either one.

As applicants have made clear in the past, Lum is directed to a system that determines the depth of penetration of a hypodermic needle or lancet for blood sampling purposes. (This is clear throughout Lum; however, see specifically Col 1 lines 7-10, Col 1 lines 49-51, for example.) The depth of penetration is determined in Lum by measuring resistance or conductivity over a very short distance of tissue being penetrated. (See Figure 2A, showing a greatly-enlarged needle cross-section that shows the electrically-conductive wire 123 separated from the electrically-conductive coating 115. As typical hypodermic needles have diameters under about 1.2 mm (see http://www.surgicalsindia.com/hypodermic-needles.html) (and 1.2 mm is very large for such needles), the distance separating the wire and coating will generally be less than 0.6 mm. Lancets are similarly sized, with diameters typically under 0.8 mm (see http://www.watl.bham.ac.uk/WASP/LANCETS/Choosi~1.htm), and hence a maximum measuring distance in the Lum system of 0.4 mm.) Thus, as is abundantly clear to one of skill in the art, Lum is directed to a system that measures penetration depth of a lancet or needle by measuring tissue resistance over a relatively short distance of less than 0.6 mm.

In contrast, the Rentea system is not designed to measure depth of penetration, but is clearly designed to measure resistance between one point on the surface of the skin to another point on the surface of the skin. (See Paragraph [0002] that clearly specifies that resistance is measured "on the skin," not during penetration.) Specifically, Rentea clearly and specifically discloses that the device described measures resistance between two electrodes 106 and 108 that are illustrated as being separated by several inches (a distance at least 100 times larger than the distance over which resistance is measured in Lum). (See the Figure and Paragraph [0016] lines 1-10.) As one of skill in the art of measuring electrical characteristics of meridians knows and would clearly understand from Rentea, the device of Rentea is specifically for use for measuring resistance at or "on the skin" and not by penetrating under the skin to the point where blood is accessed. (Paragraph [0002])

To make this point clear, Applicants include a scientific article discussing various human tissue conductivities (conductivity is inversely related to resistance, as is well-known in the art). The article is Electric Properties of Tissues, by Damijan Miklavcic et al. and is available at http://lbk.fe.uni-lj.si/pdfs/webt2006.pdf. This article illustrates the principles as to how the Lum device functions and also illustrates why using a penetrative device of Lum would prevent the system of Rentea from functioning.

Specifically, Applicants refer to Table 1 on page 11 of the Miklavcic article, reproduced below, that illustrates the conductivity of various tissues:

Table 1. Data Ranges of Specific Conductivities and Relative Permittivities of Some Other Tissues in the Low-Frequency Range (10,12,13,27,28,30,32–36,39–44)

	Spec. Conductivity (S/m)	Rel. Permittivity
Tumor	0.22–0.4	69 000 (at 1 kHz)
Fat	0.02–0.04	10 000 000 (at 10 Hz)
Muscle		
Transversal	0.04–0.34	1 500 000–10 000 000 (at 10 Hz)
Longitudinal	0.3–0.8	10 000 000–60 000 000 (at 10 Hz)
Skin (dry)	0.00002–0.0002	1 400–8 600 (at 10 Hz)
Stratum corneum	0.0000125	10 000 (at 2 Hz)
Lower-lying layers	0.227	1 100 000 (at 2 Hz)
Bone	0.01–0.06	40 000–1 300 000 (d.c.)
Blood	0.43–0.7	3 000 (at 1 kHz)
Heart	0.06–0.4	7 000 000–20 000 000 (d.c.)
Kidney	0.6	30 000 000 (d.c.)
Liver	0.023–0.2	15 000 000–50 000 000 (d.c.)
Lung (inflated)	0.024–0.09	10 000 000 (d.c.)
Spleen	0.043	45 000 000 (d.c.)
Gray matter	0.035	50 000 000 (d.c.)
White matter	0.022	30 000 000 (d.c.)

Specific conductivities are given for direct current measurements (0 Hz); measuring frequencies for relative permittivities are stated in brackets.

As can be seen from the Table, the conductivity of dry skin is orders of magnitude lower than the conductivity of any underlying tissues (i.e. the resistance of the skin is orders of magnitude higher than the resistance of any underlying tissues because of the inverse relationship of conductivity and resistance). Specifically, the dry skin has a conductivity of 0.00002-0.0002 S/m, while the underlying tissues have conductivity of approximately 0.02 S/m and higher. This clearly shows that the skin has a resistance that is at least 100 times larger than the underlying tissue. As one of skill in the art would instantly appreciate, adding a device that penetrates the skin to the meridian-resistance-measuring system of Rentea (or any other similar meridian-resistance-measuring device) would instantly and completely destroy the function of the meridian-measuring system, as the measurements would be off by a factor of approximately 100 and would therefore be absolutely meaningless.

For this reason, Applicants respectfully submit that one of skill in the art would never see a purpose to combine Lum and Rentea, would recognize that the system of Lum would destroy the purposes of Rentea, and would recognize that the systems of Lum and Rentea are inherently incompatible. Therefore, one of skill in the art would not expect success in combining Lum and

Rentea for any reason, let alone to arrive at the claimed invention. M.P.E.P. Section 2143.01 specifically states that a "proposed modification [to the prior art reference] cannot render the prior art unsatisfactory for its intended purpose." As the proposed combination of Rentea and Lum renders Rentea unsatisfactory for its intended purpose, any rejection based on the combination of Lum and Rentea is improper.

In addition, Applicants note that the Examiner has failed to provide an adequate motivation to combine the cited references. For a rejection made under 35 U.S.C. § 103, the motivation to combine must be "found in the prior art." *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). Additionally, the showing of the motivation to combine must be "clear and particular." M.P.E.P. § 2142. In the Office Action, the Examiner proposed the combination as being obvious because "such a modification would provide a means for measuring electrical signals on the skin of a patient," without citing to any portion of either Lum or Rentea as teaching this motivation to combine. As set forth above, one of skill in the art would not be so motivated. Nothing in Rentea or Lum suggests that obtaining blood samples is easier at meridians. Therefore, using the penetrating blood-obtaining needle or lancet of Lum at a meridian would provide absolutely no discernable benefit to the Lum system. As set forth above, providing a penetrating needle/lancet and electrode of Lum to the system of Rentea would destroy the purpose of Rentea. Therefore, the Examiner's proposed motivation fails to support the proposed combination in any way.

For these reasons, Applicants respectfully request the removal of any rejection relying on a combination of Lum and Rentea, namely all rejections under 35 U.S.C. § 103(a).

Furthermore, Applicants respectfully submit that one of skill in the art would not be motivated to combine additional references in the manner suggested by the Examiner. In the

Office Action, the Examiner proposed a combination of Lum, Rentea, and Teller, indicating that the motivation to combine the references would be for the "purpose of providing [an] abrasive surface contacting the dermal area of a patient." Applicants respectfully disagree. As is abundantly clear by reference to Lum, the Lum patent is directed entirely to a penetrative needle. As the needle is designed to penetrate tissue, Lum repeatedly emphasizes that the needle tip is not an abrasive bristly surface (as is claimed by Applicants), but is a sharp tip for penetrating. (See Col 2 lines 65-67, Col 3 line 66-Col 4 line 2, Col 3 lines 64-65, Col 4 lines 13-14, Col 4 lines 45-46, for example, as well as the needle shapes disclosed in Figures 1, 2A, 4, 5A, 6A, 6B, 7A, 7B, 8, and 9.) In contrast, the sensor disclosed in Teller does not rely on penetration of the skin, penetration is undesirable for that sensor, and the large sensor is not capable of penetrating the skin absent the infliction of undesirable blunt-force trauma to the user. One of skill in the art would never think to put the large bumpy surface of Teller on the end of a needle such as that disclosed in Lum as the surface would instantly and completely prevent the needle of Lum from performing its primary function.

Applicants therefore respectfully submit that one of skill in the art would not be motivated to combine Lum, Rentea, and Teller, and would not expect success in doing so. Instead, Applicants respectfully submit that the Examiner must be relying on impermissible hindsight reasoning to attempt to reconstruct Applicants' claims in a way that is not allowable. "Hindsight reconstruction" cannot be used "to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention." *Ecolochem, Inc. v. S. California Edison Co.*, 227 F.3d 1361, 1371 (Fed. Cir. 2000) (quoting *In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988)). Rather, "the best defense against hindsight-based obviousness analysis is the rigorous application of the requirement for a showing of a teaching or motivation to combine the prior art references." *Id.*

"Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability-the essence of hindsight." *Id.* (quoting *In re Dembiczak*, 175 F.3d 994 (Fed. Cir. 1999)). That hindsight reconstruction was used here is evident from the fact that the Examiner did not rely on any particular disclosure from either Lum or Teller as providing the alleged motivation to combine references.

Applicants also respectfully note that the Examiner has cited no passage of Lum, Rentea, or Anderson that shows any particular motivation to combine the references in the manner suggested by the Examiner. Rather, the Examiner merely indicates that one of skill in the art would combine the references "for the purpose of providing an audible indication of the dermal area with substantial electrical signal." Again, Applicants respectfully submit that the Examiner has relied on impermissible hindsight reconstruction in making the proposed combination. The system of Anderson relies on a change in the audible frequency to alert a user that a proper skin location has been found. For a human user to detect and respond to such a change in frequency takes a fairly long amount of time that is perfectly acceptable in a non-penetrative environment where a non-penetrative electrode such as the one disclosed in Anderson is being passed over the surface of the skin. In contrast, it is entirely improper in an invasive penetrative procedure such as the one disclosed in Lum where a needle is penetrating the skin of a patient and causing pain. In fact, Lum teaches away from such a long response delay to the penetration time based on an auditory frequency response. (See Lum Col 1 lines 16-21.) As anyone familiar with the lancets frequently used by diabetics for blood sampling, and to which Lum is addressed in part (Col 1 lines 28-30), prolonging the penetration of the lancet as depth is measured by listening to an auditory frequency change is simply undesirable and unacceptable. Therefore, Applicants

respectfully submit that one of skill in the art would not be motivated to combine Anderson with Lum and Rentea to obtain an auditory signal for Lum's penetrating needle system when the computer system already disclosed by Lum can automatically respond almost instantaneously. (Col 3 lines 24-27)

Therefore, because there is no motivation to combine references in the manner proposed by the Examiner, and because one of skill in the art would not expect success in arriving at the claimed invention by making the proposed combination, Applicants respectfully submit that the claims are not made obvious by the cited combination of references. Applicants therefore respectfully request removal of all rejections under 35 U.S.C. § 103(a).

CONCLUSION

Applicants submit that the amendments made herein do not add new matter and that the claims are now in condition for allowance. Accordingly, Applicants request favorable reconsideration. If the Examiner has any questions or concerns regarding this communication, the Examiner is invited to call the undersigned.

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Respectfully submitted,

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